

### **Remarks/Arguments**

The foregoing amendments to the claims are of formal nature, and do not add new matter. Claims 119-131 are pending in this application and are rejected on various grounds. Claims 124-129 have been indicated as allowable. Claims 119, 120 and 128 have been canceled without prejudice or disclaimer. Claims 121-124 have been amended for clarity and with the functional recitation: "wherein, the nucleic acid encoding said polypeptide is amplified in lung or colon tumors." Claim 130 has been amended for proper claim dependency. The rejections to the presently pending claims are respectfully traversed.

### **Priority**

Applicants submit that they rely on the gene amplification assay for patentable utility which was first disclosed in U.S. Provisional Application 60/141,037, filed June 23, 1999, priority to which has been claimed in this application. Based on the disclosure of SEQ ID NO: 29, Figure 20, that encodes PRO943 in Application 60/141,037, Applicants believe that the application provides adequate support and that meets the requirements of 35 USC § 101 and 112, first paragraph. Hence, Applicants should be entitled to at least an effective filing date of **June 23, 1999**.

### **Specification**

The title of the invention has been changed to more accurately reflect the present invention.

The disclosure was objected to by the Examiner as containing "embedded hyperlink and/or other form of browser-executable code." The foregoing amendment to the specification which deleted all embedded hyperlinks, is believed to overcome the present objections.

In addition, amendments to the specification have incorporated the requisite assurances that "all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the pertinent U.S. patent."

Accordingly, Applicants believe that all objections to the specification has been overcome.

### **Information Disclosure Statement**

Applicants submit an IDS separately enlisting references recited in the Blast report filed 3/25/2002 in order to be compliant with 37 C.F.R. § 1.98(a)(1). Consideration of this Information Disclosure Statement is respectfully requested.

### **Claim Rejections – 35 USC 112, first paragraph**

Claims 119-123, 130-131 are rejected under 35 U.S.C. §112, first paragraph allegedly because "the specification, while is enabling for a full length PRO943 protein of SEQ ID NO: 119, does not reasonably provide enablement for a polypeptide at least 80-99% identical to SEQ ID NO: 119. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims". For the reasons outlined below, Applicants respectfully disagree.

Applicants have canceled claims 119-120 and hence these rejections are moot with respect to these claims. As discussed under the section on "priority", Applicants rely on the gene amplification data for patentable utility for the PRO943 protein. The instant invention, defined by the claims, concerns polypeptides having 90%, 95% or 99% sequence identity with the disclosed polypeptide sequence SEQ ID NO: 119 and further, with a functional recitation: "wherein the nucleic acid encoding said polypeptide is amplified in lung or colon tumors." Based on the detailed description of the cloning and expression of variants of PRO943 in the specification, the description of the gene amplification assay and description of testing the ability of test variant polypeptides in the assay, the actual reduction to practice of sequence SEQ ID NO: 119 and the functional recitation in the instant claims, Applicants submit that one of skilled in the art would know how to make and use the claimed variants, as a lung or colon tumor marker.

Thus, Applicants request that the present 35 U.S.C. §112, first paragraph rejections to the pending claims be withdrawn.

### **Claim Rejections – 35 USC § 112, first paragraph- written description**

Claims 119-123, 130 and 131 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. The Examiner asserts that the claims are drawn to polypeptides at least 80-99% identical to SEQ ID NO:119 and thus are genus claims. The Examiner further asserts that the specification does not indicate what distinguishing

attributes are shared by the member of the genus. Applicants respectfully traverse this rejection to the pending claims.

### **The Legal standard for Written Description**

The well- established test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." In re Kaslow, 707 F.2d 1366, 1375, 212 USPQ 1089, 1096 (Fed. Cir. 1983); see also Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. see e.g. Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. Union Oil v. Atlantic Richfield Co., 208 F. 3d 989, 996 (Fed. Cir. 2000).

### **Arguments**

Applicants have canceled claims 119-120 and hence these rejections are moot with respect to these claims. As noted above, whether the Applicants were in possession of the invention as of the effective filing date of an application is a factual determination, reached by the consideration of a number of factors, including the level of knowledge and skill in the art, and the teaching provided by the specification. The inventor is not required to describe every single detail of his/her invention. An Applicant's disclosure obligation varies according to the art to which the invention pertains.

The instant invention, defined by the claims, concerns polypeptides having 90%, 95% or 99% sequence identity with the disclosed polypeptide sequence SEQ ID NO: 119 and further, with a functional recitation: "wherein the nucleic acid encoding said polypeptide is amplified in lung or colon tumors." The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a

highly skilled artisan as of the date the invention was made. Based on the detailed description of the cloning and expression of variants of PRO943 in the specification, the description of the gene amplification assay and description of testing the ability of test variant polypeptides in the assay, the actual reduction to practice of sequence SEQ ID NO: 119 and the functional recitation in the instant claims, Applicants submit that one of skilled in the art would know that Applicants possessed the invention as claimed in the instant claims.

Hence, Applicants submit that this rejection should be withdrawn.

#### **Claim Rejections – 35 U.S.C. §102**

1. Claims 119-120 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S.P.N. 6,242,419, Strachan *et al.* (dated 2001; priority date 25 Mar 1999). Applicants respectfully traverse this rejection.

2. Claims 119-123 are rejected under 35 U.S.C. §102(b) as being anticipated by Wiedemann (2000). Applicants respectfully traverse this rejection.

Applicants have canceled claims 119-120 and hence these rejections are moot with respect to these claims. As to the remaining claims, they are entitled to at least a priority date of Application 60/141,037, filed **June 23, 1999**, therefore Wiedemann is not prior art and hence, this rejection should be withdrawn.

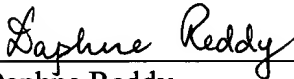
The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-2730P1C7).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: August 4, 2004

  
\_\_\_\_\_  
Daphne Reddy  
Reg. No. 53,507

**HELLER EHRMAN WHITE & McAULIFFE LLP**

**Customer No. 35489**

275 Middlefield Road

Menlo Park, California 94025

Telephone: (650) 324-7000

Facsimile: (650) 324-0638

2046213